REMARKS

Claims 1- 28 are pending in this application. Applicants respectfully request reconsideration of this application in view of the following remarks. In particular, Applicants respectfully submit that the applied references do not disclose or suggest all the features of Applicant's claimed subject matter for the reasons stated below.

I. Rejection under 35 U.S.C. §102

The Office Action rejects claims 1-6 and 12-16 under 35 U.S.C. §102(e) over Santini, Jr. et al. (U.S. Patent No. 6,491,666 A, hereinafter as "*Santini*"). This rejection is respectfully traversed.

The test for anticipation under section 102 is whether each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants' independent claim 1 recites a "medical device for controlled release of one or more substances into a body cavity containing an electrolytic fluid comprising, (a) a power supply having first and second terminals; (b) a plurality of blister-like vesicles mounted on a first surface, each vesicle having at least a metallic portion formed from a first metal; (c) for each vesicle, an electrical connection between the metallic portion of the vesicle and the first terminal of the power supply, each connection including a switch so as to allow the metallic portion to function as an anode when the switch is closed; and (d) a cathode formed from a second metal attached to the second terminal of the power supply; *wherein the cathode is separated from the anodes by a space that is assessable by the electrolytic fluid when the device is in the body cavity.*" (Emphasis added)

In contrast, *Santini* is directed to a microchip chemical delivery system primarily designed for intravenous and external applications, such as for diagnostic purposes or for the

non-medical purpose of fragrance delivery. (see FIGS. 8A-8C, 10A-12 and col. 4, lines 7-15, for example). Only one medical device in *Santini* is intended for implantation in the body, namely, the stent as shown in FIGS. 9A-9C and described specifically at col. 15, lines 7-42. All of the other medical devices to which *Santini* is drawn release substances into a carrier fluid, which is ten infused into the body.

In all of the embodiments of *Santini*, there is no discussion of a "cathode... separated from ... anodes by a space that is assessable by ... electrolytic fluid when the device is in the body cavity" as presently claimed. In fact, *Santini* is completely silent about the use of an electrolytic body fluid. In contradistinction to the present claims, the microchip system of *Santini* is based on a semiconductor device that does not use an electrolytic body fluid to provide conductivity between the anode and the cathode (in contradistinction to the present claims). The device is shown in FIG. 2a with a substrate 210, in which reservoirs 220 are filled with molecules to be released 240. Reservoirs 220 are covered by reservoir caps 230 and sealed with backing plate 250 or other type of seal. (see col. 4, lines 25-29) The "release" system material can be selected so that molecules of various molecular weights are released from a reservoir by diffusion out of or through the material or by degradation of the material. (see col. 5, lines 51-54) In other modes, conductive materials capable of dissolving into solution can be used as anodes and cathodes (see col. 6 line 62 to col. 7 line 15). However, neither passage suggests how electrical conductivity can occurs between an anode and a cathode, and since the passage is not drawn to an implanted device, it obviously does not mention utilizing an electrolytic body fluid to provide conductivity between the anode and the cathode, as would occur under the presently claimed structure.

Despite this, the Examiner has asserted that such a claimed feature may be seen in FIGs. 2a – 2d of *Santini*. Of FIGs. 2a to 2d, only FIG. 2d has an anode and a cathode. (see col. 4 lines 46 – 67, which erroneously refer to "FIG. 4d" but are clearly drawn to FIG. 2d) In FIG. 2d, electrolysis is used to dissolve an anode 530b separating two reservoirs (520a and 520b) in order to allow mixing of the contents of the two reservoirs. The description in no way indicates the mechanism by which the reservoir cap 530a is dissolved. Moreover, as noted above, the

description does not disclose how electrical conductivity can occurs between the anode and cathode, and since FIG. 2d and its description are not drawn to implanted devices, it obviously does not mention utilizing an electrolytic body fluid to provide conductivity between the anode and the cathode, as would occur under the presently claimed structure. Moreover, the specification gives no indication that the device of FIG. 2d, even if *arguendo* implanted in a body cavity containing an electrolytic fluid, would make both the anode and the cathode accessible to the fluid.

Various other modes of release are described, but these also all differ from the present claims. One particular mode is described in FIGS. 3A-3C, which illustrates the active release of molecules into a liquid carrier from a microchip that releases molecules in response to electrochemical stimulation. The application of an electrical potential causes the cap material to dissolve, providing for the release of the molecules into the liquid flowing adjacent to the reservoir opening. (see col. 11, lines 61-67). The molecules are released into a liquid carrier, which transports the molecules to the target. Again, there is no mention of an electrolytic body fluid between the anode and the cathode, as claimed by the Applicants. Another mode is described with reference to col. 14 lines 8 – 45, an intravenous delivery system which is not implantable, and which makes no reference to an "anode" whatsoever. Once again, there is no mention of an electrolytic body fluid between the anode and the cathode, as would occur under the presently claimed structure.

This is the sum total of the complete disclosure regarding the mechanism for an electrically activated release in *Santini*.

Accordingly, as *Santini* does not disclose, teach, or suggest a cathode separated from anodes by a space that is assessable by electrolytic fluid when the device is in the body cavity, as recited in claim 1, Applicants respectfully submit that *Santini* does not disclose or suggest all the features of Applicants' independent claim 1. As such, *Santini* does not anticipate claim 1.

Claims 2-6 and 12-16 depend from claim 1. Therefore, for at least the above reasons, Applicants respectfully request the withdrawal of this rejection.

II. Rejections under 35 U.S.C. §103

The Office Action separately rejects claims 7-11, claim 17, claims 18-24, claim 25, and claims 26-28 under 35 U.S.C. §103(a) over *Santini* in view of Yachia et al. (U.S. Patent No. 6,293,923, hereinafter as "*Yachia*"). These rejections are respectfully traversed.

To establish a *prima facie* case of obviousness, the Examiner must establish: (1) some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) the prior art references teach or suggest all of the claim features. *Amgen, Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); *In re Fine,* 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970).

Yachia is directed to an inflatable surgical balloon for urinary tract infections. The balloon contains a valve 5 wherein fluid is injected into the lumen 4 to cause the balloon to expand. The balloon 1 is clutched by flanges 23 which are initially kept closed by constraining sleeve 26 to enable release of the balloon 1 into the bladder. (see col. 5, line 42 to col. 6, line 13)

It is readily apparent that there is no disclosure or suggestion in *Yachia* regarding the subject matter lacking in *Santini* as discussed above. Accordingly, *Yachia* does not cure the deficiency of *Santini*. Therefore, *Santini* and *Yachia*, individually or in combination, do not disclose or render obvious all the features of Applicants' independent claim 1. As such, the Examiner has failed to prove a *prima facie* case of obviousness of claim 1 over *Santini* and *Yachia*.

Claims 7-11, 17, 18-24, 25, and claims 26-28 all depend from claim 1. Therefore, Applicants respectfully submit that all of the rejected dependent claims are not anticipated or rendered obvious in view of *Santini* and *Yachia*. Accordingly, for at least the above reasons, Applicants respectfully request the withdrawal of the rejection of claims 7-11, claim 17, claims 18-24, claim 25, and claims 26-28.

CONCLUSION

In light of the foregoing, Applicants submit that the application is in condition for allowance. If the Examiner believes the application is not in condition for allowance, Applicants respectfully request that the Examiner call the undersigned.

Respectfully submitted,
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